

Transcatheter Closure of Cardiac Defects with Lifetech™ Konar-Multifunctional Occluder Experience in a Tertiary Care Center

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ABSTRACT

Objective: To assess the immediate and short-term efficacy and safety of transcatheter closure of cardiac defects with Lifetech™ Konar-MFO in a Tertiary Cardiac Care Center.

Study Design: Descriptive cross-sectional study.

Setting and Duration of Study: Armed Forces Institute of Cardiology/National Institute of Heart Diseases, Rawalpindi Pakistan, from Mar 2019 to Dec 2021

Methodology: Patients of all ages and both gender undergone transcatheter closure of a cardiac defect with Konar-MFO from Jan 2021 to Dec 2021 were included in the study through non-probability consecutive sampling and approval by the institutional ethical review committee was taken prior to data collection. Data of patients undergone transcatheter closure with Konar-MFO from Mar 2019 to Dec 2020 was extracted retrospectively to assess the immediate and short-term efficacy and safety of the occluder. SPSS version-23 was used for data entry and analysis.

Results: A total of 138 patients had transcatheter closure of a cardiac defect with Lifetech™ Konar-MFO during the study period. Case of VSD were 124(89.9%), PDA 9(6.5%), post-operative cases were 4(2.9%) along with 1(0.7%) case of coronary artery fistula (CAF) to the right ventricle. Out of 138 patients, 73(52.9%) were females while 65(47.1%) were males. The mean age was 9.3 ±8.1 years with a range of 6 months to 36 years. Mean fluoroscopy time was 13.68±9.74 min. The procedure was successful in 137(99.27%) cases. The device embolized in 2(1.45%) cases.

Conclusion: In selected cases of VSD, PDA and in some post-operative cases the occlusion with Lifetech™ Konar-MFO is safe and efficacious with the added benefits of softness and versatility of the approach.

Keywords: Congenital Heart Disease, Transcatheter Closure, VSD (Ventricular Septal Defect).

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INTRODUCTION

Congenital heart disease is the most common developmental anomaly occurring in 8 cases per 1000 live births.¹ Ventricular septal defect (VSD) accounts for 30-40% of children with congenital heart disease and has a prevalence of 3.3 per 1000 live births.^{2,3} Spontaneous resolution of VSD has been described both prenatally and in the postnatal life up to 5 years of age particularly when the membranous part of the septum is not involved.⁴ Symptomatic patients with large VSDs, not amenable to transcatheter closure, presenting with failure to thrive, congestive heart failure, recurrent chest infections and exercise intolerance need timely surgical closure of the defect to prevent pulmonary vascular obstructive disease. Small sized VSDs and moderate VSDs with a restrictive shunt, over time can lead to progressive aortic regurgitation, dual chambered right ventricle and bacterial endocarditis.⁵ VSD patch plasty has an excellent

outcome with reported mortality rate of 0.3 to 0.6%. Transcatheter closure technique, where possible, avoids sternotomy and bypass injury, needs shorter hospital stay and medical cost.⁶ Presently the transcatheter technique for closing selected cases of VSD is being practiced in increasing number of patients across the globe including cases of residual VSDs, especially when surgical reintervention might be risky.^{7,8} The technique is continuously being refined and is currently in routine use in Armed Forces Institute of Cardiology, Rawalpindi where a variety of VSD occluders have been successfully used over the past few years.⁹

Lifetech™ Konar-Multifunctional occluder (MFO) is a relatively new VSD occluder and has been known for its versatility and ease of using.¹⁰ It is a double disc device in which the two discs of unequal size are joined by a waist corresponding with the size of the VSD (Figure-1). Apart from its conventional use as VSD occluder, the versatility of the device allows its use in patent ductus and coronary fistula also.¹¹

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The present study describes our experience with using Lifetech™ Konar-MFO in our centre over the past three years. The findings of this study will give us an opportunity to compare the outcome of using Lifetech™ Konar-MFO with other occluders, help us improve our current practices and serve as a local study for other cardiac centres in the country.

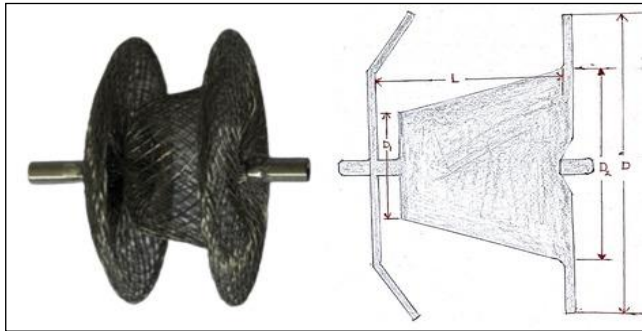


Figure-1: Konar-MFO along with its diagrammatic representation showing the two connecting hubs D. Diameter of the disc. D1. Diameter of the waist on RV side. D2. Diameter of the waist on LV Side. L. Length of the waist. (Adapted from Grolier CG *et al*)¹²

METHODOLOGY

This descriptive, cross sectional study was carried out in the department of Paediatric Cardiology at Armed Forces Institute of Cardiology, Rawalpindi Pakistan, from Jan 2021 to Dec 2021. Data from Mar 2019 to Dec 2020 was also retrospectively included in the study. Approval of the institutional ethical review board was obtained from R&D department AFIC/NIHD (letter number 26/1/R&D/2022/144). By considering 9.8% prevalence, the patients in whom transcatheter occlusion of a cardiac defect was carried out with Lifetech™ Konar-MFO were included in the study by non-probability consecutive sampling by considering the anticipated frequency of 9.9%.

Inclusion Criteria: Patients having isolated perimembranous (with or without membranous septal aneurysm) or muscular VSD affecting haemodynamic status, age more than 6 months, in case of perimembranous VSD, the upper margin of the defect and aortic valve distance >2 mm or >2.5 mm depending upon the size of the occluder used, no aortic valve prolapse or regurgitation at presentation.

Exclusion criteria: Extensive cardiac anomalies needing cardiac surgery, thrombus near the VSD or in vessels of access, endocarditis, likely interference with aortic or either of the atrio-ventricular valves, aortic valve prolapse or regurgitation and severe pulmonary vascular disease.

The procedure was performed under general anesthesia in patients up to 16 years of age while local anesthesia was used in adults fulfilling the inclusion criteria. Depending upon the approach used, whether antegrade or retrograde, femoral venous and arterial access or two femoral arterial lines respectively were used. Left ventricular (LV) angiogram was done with a pigtail catheter in different angles ranging from 25° to 90° left anterior oblique/20° cranial projection depending upon the location and profile of the defect. After locating the defect, it was engaged with either Judkins right heart or a cut pigtail catheter depending on the location, and was crossed with a 0.035" Terumo guide wire, and arteriovenous loop formed (if antegrade approach planned) after snaring the wire in either pulmonary artery, SVC or IVC and bringing it out of femoral vein, thus providing a railroad for advancing the delivery system across the defect from the right ventricle (RV) side and bringing the tip of the delivery sheath till the descending aorta, using the kissing catheter technique. In case of a retrograde approach, after crossing the defect from LV side, the delivery sheath was advanced through the femoral artery and across the defect till the mid RV cavity.

Echocardiography was carried out using Philips iE 33 with a 5MHz transducer or Siemens Acuson SC2000 Prime with a 4MHz transducer. Transesophageal echo was done in case of poor windows encountered especially in adult patients. Size selection of the occluder was done using both echocardiographic and angiographic assessment.

In case of aneurysmal defects the aim was to fit the PDA part of the device snugly into the aneurysm using antegrade approach for better stability and control of the desired deployment. For defects with no aneurysm the device was deployed such that the PDA part of the device would snugly occlude the defect, again using the antegrade approach. Retrograde approach was used in cases having VSD not very close to the aortic valve. Immediate post occlusion assessment was done before releasing the device by using echo-cardiographic, fluoroscopic and ECG guidance for residual leak, aortic and tricuspid incompetence and any rhythm or conduction abnormalities.¹³ Efficacy was defined as the absence of severe residual shunt around the device. Safety was defined as the absence of death or major adverse effects due to procedure. Adverse effects were untoward effects either because of the procedure (procedure related adverse effect PRAE) or the device (device related

adverse effect DRAE). They were categorized as minor if they were non-fatal and settled with treatment including haematoma formation, mild haemolysis, and transient heart blocks. Major adverse effects were death due to procedure, life threatening injury or illness or any event requiring surgery like embolized device, trauma to myocardium, ruptured vessel, severe hemolysis, severe residual shunt, valvular trauma or persisting complete heart block needing a permanent pacemaker. The extent of residual shunt was defined as minimal (<1mm), mild (1-2mm), moderate (2-4mm) and severe (>4mm) based on the thickness of the colour jet through the septum asse-ssed by echocardiography.¹⁴ The patients included in prospective part of the study had a short term follow up in the ward for any adverse effects or complications with ECG and transthoracic echocardiography at 6 and 24 hours after the procedure. Patients who underwent occlusion of cardiac defect with MFO device from March 2019 to Dec 2020 were also retros-pectively included in the study to complete the data for three consecutive years.

Data was entered and analyzed with the help of statistical package for social sciences (SPSS) version 21. The categorical data was presented as frequencies and percentages, whereas, continuous data was depicted as means and standard deviations.

RESULTS

A total of 138 patients had transcatheter closure of a cardiac defect with Lifetech™ Konar-MFO during the study period. Among them VSD were 124(89.9%), PDA were 9(6.5%), post operative cases were 4(2.9%) and 1 case (0.7%) was that of coronary artery fistula (CAF) to the right ventricle. The postoperative cases included 2(1.4%) cases of Tetralogy of Fallot (TOF) with residual shunts, 1(0.7%) case of post bidirectional Glenn (BDG) for occluding antegrade flow and 1(0.7%) case of post Fontan fenestration occlusion. Out of 138 cases 23(16.67%) were performed in 2019, 41(29.71%) in 2020 and 74(53.62%) in 2021 (Table-I).

The number of females and males in study population was 73(52.9%) and 65(47.1%) respectively. The mean age was 9.3±8.1 years with a range of 6 months to 36 years. The procedure was performed under general anesthesia in 120(87%) cases and under local anesthesia in 18(13%) cases.

Retrograde approach (Figure-2) was used in 88 (63.8%) while antegrade approach (Figure-3) was utilized in 50(36.2%) cases. Size 5F and 6F were used for venous access while size 4F, 5F and 6F were used for the arterial access. Mean fluoroscopy time was

13.68±9.74 minutes with a range of 2.2 to 61.5 minutes. Mean contrast used was 74.78±34.02ml.

Table-I: Yearly distribution of cardiac defects treated with Konar-MFO along with mean fluoroscopy time

Year n(%)	Anomaly	Number n(%)	Mean Fluoro time Min±SD
2019 23(16.67)	VSD	21(15.22)	11.5±11.9
	PDA	2(1.45)	6.5±3.5
2020 41(29.71)	VSD	37(26.81)	13.9±10.3
	PDA	2(1.45)	10±5.0
	CAF	1(0.72)	30±0.0
	Post Fontan	1(0.72)	20.12±0.00
2021 74 (53.62)	VSD	66(47.83)	14.3±8.5
	PDA	5(3.62)	6.14±1.17
	Post-op TOF	2(1.5%)	29.2±14.4
	Post BDG	1(0.72)	22±0.00

VSD=Ventricular septal defect; PDA=Patent ductus arteriosus; CAF=Coronary artery fistula; TOF= Tetralogy of Fallot; BDG= Bidirectional Glenn Shunt

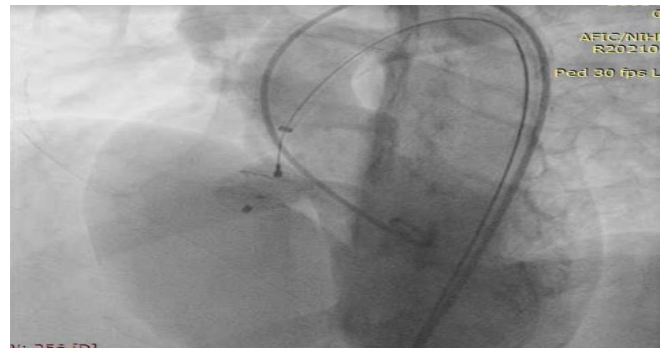


Figure-2: Retrograde approach showing device occluding the defect with delivery cable attached to the LV disc

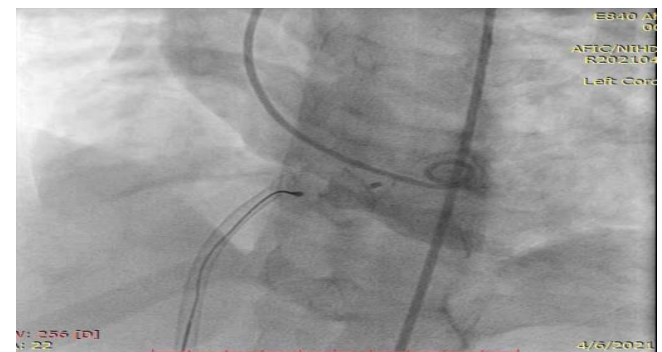


Figure-3: Conventional antegrade approach used with MFO. Delivery cable attached to RV disc

The procedure was successful in 137(99.27%) cases. The device embolized in 2(1.45%) cases. The first case of device embolization was an 11 years old female with retrograde approach a small 6x4mm device was used at first and later a larger 8x6mm which embolized to left pulmonary artery (LPA) and was retrieved. The

procedure was abandoned after a fluoroscopy time of 61.5 minutes, the longest in three years. In the other case of device embolization, a 13 years old male, the 7x5MFO embolized to LPA, was successfully retrieved and replaced with 12x10 successfully. In both the embolization cases the reason was underestimation of the size of the defect. A 6 years old girl with VSD went into cardiac arrest during the procedure while crossing the defect from LV side and was successfully revived. All other cases were uneventful and were discharged from hospital without any immediate complications.

DISCUSSION

Transcatheter closure of small to moderate sized ventricular septal defects amenable to percutaneous closure, has gradually become safer and easier and is more acceptable as compared to open heart surgery with the hazards of bypass.^{15,16} However as every procedure has attendant complications, this procedure is no different.¹⁷ Over a period of time many devices have been devised to effectively close the defect without any short term or long term untoward effects.^{18,19} Lifetech™ Konar-MFO is a relatively newer and versatile device which has shown promising results in both perimembranous and muscular ventricular septal defects along with selected cases of patent ductus arteriosus.²⁰

Lifetech™ Konar-MFO has the advantage of double screwing hub which makes using the retrograde approach possible despite it is not a symmetrical device.¹⁰ The main advantage of the retrograde approach is that the aortic valve is kept safe, no snare is needed in the equipment and thus no need to form an AV loop, which significantly cuts down on fluoroscopy time and thus general anesthesia time.²¹ However there's need for two arterial lines thus doubling the chances of peripheral limb ischemia.

Over the course of three years (2019-21), we successfully used Lifetech™ Konar-MFO in 9 cases of PDA with successful deployment, no definite evidence of obstruction to the nearby structures and no immediate or short term adverse effects. The lack of obstruction of the nearby structures is apparently because the device is softer with a flexible waist adding to the ease of fitting in to the defect.¹² We also successfully closed a 2mm coronary artery fistula to the right ventricle using a 5x3 Konar-MFO device. The VSD cases included three cases of doubly committed VSDs. Apart from VSD, PDA and CAF we also successfully dealt with two post-operative cases of TOF with residual leak, one case of post BDG for

occlusion of antegrade flow by deployment of the occluder in RVOT and one case of post Fontan fenestration occlusion again an evidence of the versatility of Konar-MFO device.

As with other devices, the antegrade approach can also be used as it provides more stability and control over deployment in aneurysmal defects and the waist of the device snugly fills the defect with more ease. However we recommend that echo guidance be used when deploying RV disc as it could easily be deployed above the tricuspid valve due to the longer length of the device as compared to other devices. We had one such case, the device was recaptured and redeployed after documenting tricuspid regurgitation in post procedure echo. But in subsequent cases intra procedure echo guidance was used for successful deployment.

Device embolization and infective endocarditis are known risks of transcatheter closure of VSD and have been reported in 1-3% and 0-0.3% of cases respectively.^{22,23} We had two cases of device embolization (1.45%) and none of infective endocarditis. In one case of device embolization the procedure was unsuccessful because it had to be abandoned owing to increasing fluoroscopy time despite the embolized device was successfully retrieved from the left pulmonary artery. In our experience, retrieval of an embolized MFO was twice as easier compared to other occluders, owing to two hubs thus doubling the chances of being caught in snare.

Residual leak is a major limiting factor in transcatheter VSD closure, giving rise to intravascular hemolysis, which can be prevented by proper sizing.²⁴ Our closure rates with Konar-MFO were, however, 100% with no incidence of residual leaks.

Transcatheter closure of VSD has a known untoward effect of arrhythmias with an incidence of 10.3% among which 2.1% are likely to be permanent with the incidence of complete heart block being 1.1%.¹⁷ Because of its softness and flexibility along with a funnel shape, Konar-MFO makes it a good choice for defects in close proximity to aortic valve. This feature also reduces the chances of heart blocks because of reduced chance of conducting tissue damage. We did not have any case with post procedure block or arrhythmia. Besides, the ability for relatively larger device to be loaded into smaller sheath sizes gives the advantage of lesser arterial vascular damage. We did have a case of cardiac arrest during the procedure while crossing the VSD from LV side. The six years old

girl was successfully revived. This complication is more likely to be a procedure related adverse effect rather than attributable to Konar-MFO and is inherent to any case of transcatheter VSD closure.

Strength of Study: The strength of our study was the long study period of three years with a significantly large number of cases. It shows that Lifetech™ Konar-MFO was a versatile device which can be safely used in selected cases of VSD, PDA and even coronary artery fistula. This was in accordance with previous studies which showed the same results.^{11,25}

LIMITATIONS OF STUDY

A limitation of this study was the limited follow up duration in its prospective part because of which long term complications like late onset arrhythmias including complete heart block could not be assessed.

CONCLUSION

In selected cases of VSD, PDA and in some post-operative cases, occlusion with Lifetech™ Konar-MFO is safe and efficacious, with the added benefits of softness and versatility of approach.

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Conflict of Interest: None.

Author's Contribution

Following authors have made substantial contributions to the manuscript as under:

AA: Study design, concept and critical review

KA: Intellectual contribution, concept and final approval

AM: Drafting the manuscript, proof reading & critical review

NS: Intellectual contribution, concept and final approval

SR: Review of article, formatting and critical review

SI: Study design, concept and critical review

BA: Study design, concept and critical review

TA: Analysis, result interpretation and proof reading

HA: Review of article, formatting and critical review

AF: Review of article, formatting and critical review

Authors agree to be accountable for all aspects of the work in ensuring that questions related to the accuracy or integrity of any part of the work are appropriately investigated and resolved.

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